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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

NUTRACEUTICAL CORPORATION, et al., Plaintiffs, v. LESTER CRAWFORD, DVM, Acting Commissioner of the U.S. Food and Drug Administration, et al., Defendants.	)	Case No. 2:04CV00409 TC

PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION AND REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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I. SUMMARY

In the Final Rule, 69 Fed. Reg. 6788 (February 11, 2004)(hereinafter "Final Rule"), the Defendants failed to satisfy their statutory burden of proof under 21 USC § 342(f) (and thereby violated the statute) when they banned every dose level of ephedrine alkaloid-containing dietary supplements ("EDS"). They also violated the Administrative Procedure Act ("APA") prohibition on arbitrary and capricious agency action and on adoption of a substantive rule without advance notice and opportunity for comment. 5 U.S.C. §§ 553 and 706.

Violation of 21 U.S.C. § 342(f). The Defendants failed to meet their statutory burden of proof under 21 USC § 342(f): (1) by refusing to give meaning to the essential terms "conditions of use . . . suggested or recommended in the labeling . . ." and "significant" in the dietary supplement adulteration provision; (2) by failing to establish, by a preponderance of the evidence, a significant or unreasonable risk of illness or injury under *every* condition of use (including dietary supplements containing daily ephedrine alkaloid dose levels of 10mgs or less (hereinafter "Low Dose EDS")) before banning *all* ephedrine alkaloid containing dietary supplements outright; (3) by adopting a "risk/benefit" balancing test that is not a permissible construction of the dietary supplement adulteration provision; and (4) by flouting the will of Congress, which clearly intended that the dietary supplement adulteration provision be read in harmony with the food adulteration provision.

Violation of the APA Prohibition on Arbitrary and Capricious Agency Action. The Defendants also violated the APA's prohibition on arbitrary and capricious agency action (5 U.S.C. § 706): (1) by failing to articulate a standard or distinguishing principle in the Final Rule that can enable the regulated class to discern whether any dietary ingredient will not be deemed adulterated, and thus will be lawful for sale, in light of the FDA's failure to define

comprehensibly the meaning of "unreasonable risk," of "benefit," and of the nature, degree, quality and quantity of "benefit" required to counterbalance any perceived "unreasonable risk;" (2) by holding all ephedrine alkaloids to present an unreasonable risk of illness or injury without any dose dependent analysis and, in particular, without scientific proof of illness or injury at the level of 10 mgs or less of ephedrine alkaloids per day; and (3) by causing herbal ephedra when sold in a tea at ephedrine alkaloid per serving levels ranging from 15 mgs to 30 mgs[1] to remain legally saleable while banning outright the very same substance when encapsulated and sold as a dietary supplement *even when the ephedrine alkaloid dose levels in the supplement are substantially less than those in a serving of the tea.* See page 26 *infra*.

Violation of the APA Prohibition on Adoption of a Substantive Rule Without Federal Register Publication Giving Notice and Opportunity for Comment. The Defendants argue that they have not violated the APA requirement of Federal Register publication (5 U.S.C. § 553) -- requiring notice and opportunity for comment -- when they adopted an entirely new standard for evaluation of dietary supplement adulteration (the "Risk/Benefit Test") in the Final Rule. They argue that public notice that they were considering holding ephedra adulterated under the dietary supplement adulteration provision was enough. The Defendants are wrong. The Risk/Benefit Test was not a secondary or tertiary finding flowing from a principle clearly articulated in the Federal Register invitation for comments. No, the risk/benefit test is ***the central defining principle*** of the Final Rule. Only decision-makers within the FDA could have anticipated that FDA would adopt a new test for defining dietary supplement adulteration – one that would weigh "unreasonable risk" against "benefit" and find adulteration if the perceived weight of the

[1] FDA's Briefing Materials for Food Products Containing Ephedrine Alkaloids at 5 (October 11-12, 1995); 95N-0304, Vol 39, Ref. 1 (Ref. 30 to 62 Fed. Reg. 30678, "Dietary Supplements Containing Ephedrine Alkaloids, Proposed Rule")(hereinafter "Briefing Materials for Proposed Rule").

benefit was not deemed sufficient to counterbalance the perceived risk. No opportunity for comment on the test was afforded to the regulated class before its adoption.[2] The Final Rule is wholly meaningless without the test. Accordingly, the Defendants violated the APA's advance notice and opportunity for comment requirements.

As explained in detail below, in light of the Defendants' violation of 21 U.S.C. § 342(f) and the Administrative Procedure Act, 5 U.S.C. §§ 706 and 553, the Final Rule should be declared invalid, the matter should be remanded to FDA for further rulemaking consistent with the Court's opinion, and the FDA should be enjoined from taking any action to prevent the Defendants from marketing a dietary supplement containing a daily ephedrine alkaloid dose of 10 mgs or less.

[2] In the 1997 and 2003 proposed rules (62 Fed. Reg. 30678 (modified by 62 Fed. Reg. 44247) and 68 Fed. Reg. 10417), the FDA focused on establishing a dose-dependent limit on ephedrine dietary supplements, not on banning them outright. That dose dependent analysis helped lull the regulated class into expecting the Final Rule to follow the same method of analysis focusing, as the statute does, on "conditions of use...suggested or recommended in the labeling..." Instead, FDA adopted an entirely new test, the Risk/Benefit Test.

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